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510(k) Summary of Safety and Effectiveness

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Date Prepared: July 15, 2004

Trade Name: E-Tac EX-1000 Electrocardiographic Event Recorder
Common Name: Ambulatory ECG Event Recorder
Classification Name: Telephone electrocardiographic transmitter and receiver (class 2 device; 21 CFR 870.2920; product code: DXH)

Predicate Devices

- Instromedix King of Hearts Express 3x [K920984]
- Braemar ER300 series (ER300, ER310, ER320) [K923930]
- Braemar ER700 series (ER710 and ER720) [K981394]

Indications for Use

The Datrix E-Tac EX-1000 Electrocardiographic Event Recorder device is intended for long-term monitoring of ambulatory cardiac patients who experience intermittent symptoms associated with cardiac arrhythmia. Upon activation by the patient, ECG data are stored for future transmission via telephone to a receiving station. Data transmission is initiated by the patient and confirmed by the receiving station. Once data are transmitted, they are immediately available for review solely by a physician or other qualified medical professionals.

Description

The Datrix E-Tac EX-1000 (here simply: EX-1000) Electrocardiographic [ECG] Event Recorder is intended for long-term monitoring of ambulatory cardiac patients who experience intermittent symptoms associated with cardiac arrhythmia. Lightweight and compact, the EX-1000 is designed to be as non-intrusive as possible to the patient, and can operate up for 30 days on two AAA alkaline batteries. The patient's ECG data are acquired via patient leadwires (two-lead, one-channel). At the onset of an event, the patient presses the [Record] button to store his or her ECG data in the recorder's flash memory. Events are recorded according to one of four user-selectable memory configurations. Up to two events may be recorded before transmission of the data to a compatible receiving station is required. The patient initiates data transmission via telephone by removing the patient leadwires and pressing the [Send] button, upon which the stored data are transmitted. A physician or other qualified medical professional reviews the transmitted data. Feedback on the EX-1000 recorder status is provided to the user (technician and/or patient) via a multi-colored LED and audible tones.

Standards/Guidance Documents

- AAMI/ANSI EC38:1998 Ambulatory Electrocardiographs
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03
- AAMI / ANSI / IEC 60601-1-2:2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ISO 14971, "Medical devices — Application of risk management to medical devices" (December 15, 2000)
- *Partially Applicable*: Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); Final, Version 1.0, November 5, 1998.
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final, May 29, 1998.
- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, July 18, 2000.

Operational Principle(s)

The operational principles for the EX-1000 are as follows: ECG data are acquired via patient leadwires, sampled with an analog/digital converter, and subsequently saved to the flash memory. Stored ECG data are transmitted to a compatible receiving station utilizing FM Modulation and Frequency Shift Keying techniques. Transmission characteristics include carrier center frequency, carrier deviation, and transmission speeds commensurate with the predicate devices, which ensure compatibility with many commercially available receiving stations.

System Descriptions

1. Modes of Operation:
   - Monitoring mode– ECG data continuously acquired and written to flash memory in a loop. The size of the looping memory varies according to one of four selectable memory configurations.
   - Recording mode – when the patient presses the [Record] button, data are stored in flash memory until transmitted.
   - Transmission mode – data are transmitted via telephone to a compatible receiving station

2. Software - Software pertaining to the EX-1000 consists of the firmware instructions to the microcontroller for managing the different functions of the recorder. The firmware is considered to be of "minor level" of concern as evaluated using the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Final" (May 29, 1998). Software

Documentation was provided in the submission commensurate with this evaluation. The firmware was designed, documented, and validated in accordance with required device Design Controls [i.e., 21 CFR 820.30]. Risks associated with the firmware were analyzed in accordance with FDA's Guidance "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" (July 18, 2000), and ISO 14971, "Medical devices — Application of risk management to medical devices" (December 15, 2000).

Performance Testing

In addition to thorough verification and validation testing, the Datrix E-Tac EX-1000 has been tested and conforms to the following recognized performance standard for safety and effectiveness:

- AAMI/ANSI EC38:1998 Ambulatory Electrocardiographs

By the time of marketing, the Datrix E-Tac EX-1000 has and will have been further tested to conform to the following recognized safety standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03
- AAMI / ANSI / IEC 60601-1-2:2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ISO 14971, "Medical devices — Application of risk management to medical devices" (December 15, 2000)

Predicate Device Performance Comparisons

Compliance to the ISO 14971 risk assessment requirements was accomplished by demonstrating in-house conformance to safety and reliability standards for acquiring, recording and transmission of known input signals. In addition to testing to AAMI/ANSI EC38:1998, verification, and validation, a predicate comparison test was conducted between the EX-1000 and the listed predicate devices. Performance of each device was evaluated over a range of input amplitudes and frequencies. A total of 24 in-house simulated events were recorded, and subsequently transmitted twice (2 x 24), once each to two separate, commercially available receiving stations (GEMS™ Lite and EKG Speaks™). Reports were printed out from each receiving station, and multiple measurements of each transmitted event were made of 2 key data characteristics: amplitude and timing (frequency). Results are summarized as follows:

- All recorders (EX-1000 and predicates) accurately reproduced the timing/frequency of the known input signals with no variance within or between devices.
- For amplitude measurements, all devices performed to requirements and tolerances specified in the AAMI/ANSI EC38:1998 standard.

- Twelve of the 24 combinations of amplitude, frequency, and receiving station combinations tested were input signals for frequencies at 25Hz; the remaining twelve were at 40Hz. All devices showed amplitude attenuation commensurate with their bandwidth specifications.

Two in-house, three-factor ANOVA evaluations were performed separately on amplitude data from each of the receiving stations. Results and statistical analyses indicated that performance of the Datrix EX-1000 was substantially equivalent or better than the three predicate devices with regards to amplitude reproduction in nearly all combinations of input amplitudes, input frequencies, and receiving stations (total of 24 cases). The following Performance Table summarizes these statistical results:

Device	Amplitude reproduction not significantly different or better than all other devices	Amplitude reproduction not significantly different or better than at least one device	Amplitude reproduction significantly different than other devices	Statistic
EX-1000	20 of 24 cases	3 of 24 cases	1 of 24 cases†	$p < 0.001$
ER320	11 of 24 cases	13 of 24 cases	0 of 24 cases	$p < 0.001$
ER720	9 of 24 cases	8 of 24 cases	7 of 24 cases*	$p < 0.001$
King of Hearts Express	6 of 24 cases	15 of 24 cases	3 of 24 cases[+]	$p < 0.001$

† This case occurred for an input signal of 2.0mV and 0.5 Hz with measurements taken from printouts generated by the EKG Speaks™ receiving station software. For the same signal when evaluated using the GEMS™ Lite receiving station, the EX-1000 was substantially equivalent to the King of Hearts Express recorder. See the note (+) below for further explanation.

* 5 of these cases were in the high frequency range, and significantly different results may be affected by bandwidth specifications.

[+] all 3 cases were for the low frequency (0.5Hz) measurements taken using the EKG Speaks™ receiving station software. The same effect was not seen with the GEMS™ Lite receiving station. Filtering algorithms used by the EKG Speaks™ program may have affected these results.

The Comparison Tables on the following pages provide comparisons of the features and specifications of the EX-1000 device and each of the predicate devices.

Conclusion

The Datrix E-Tac EX-1000 is substantially equivalent to other predicate ambulatory ECG event recorders currently in commercial distribution.

Specification	Datrix E-Tac EX-1000	Instromedix King of Hearts	Braemar ER 300 series	Braemar ER 700 series
Intended Use	The Datrix E-Tac EX-1000 Electrocardiographic Event Recorder device is intended for long-term monitoring of ambulatory cardiac patients who experience intermittent symptoms associated with cardiac arrhythmia. Upon activation by the patient, ECG data are stored for future transmission via telephone to a receiving station. Data transmission is initiated by the patient and confirmed by the receiving station. Once data are transmitted, they are immediately available for review solely by a physician or other qualified medical professionals	(From the manual) The King of Hearts Express® 3X™ cardiac event recorder is a patient-activated device designed for diagnostic evaluation of transient symptoms such as dizziness, palpitations and chest pain. The King of Hearts Express® 3X™ has five minutes of looping ECG memory to capture ECG data both before and after the patient experiences a cardiac symptom. The frequency response is .05 to 30Hz	(From the manual) The ER300 Series Event Recorders are battery operated, solid state patient activated event recorders designed to recorder infrequent and elusive heart arrhythmias. The recorders offer ten preprogrammed recording options and will operate for a minimum of 7 days with a 9V alkaline battery.	To record infrequent and elusive ECG heart arrhythmia data. Once an event is recorded, patients transmit the recorded ECG data over the telephone. Or, as an alternative, the ER700 Series allows the ECG data to be transferred directly to a host PC if the patient returns the unit to the clinic.
Standards Performance	AAMI/ANSI EC38	unknown	unknown	AAMI/ANSI EC38
Safety	IEC60601-1 +A1 +A2	unknown	unknown	IEC60601-1 +A1 +A2
EMC	IEC60601-1-2	unknown	unknown	IEC60601-1-2

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Specification	Datrix E-Tac EX-1000	Instromedix King of Hearts	Braemar ER 300 series	Braemar ER 700 series
Operational Principles				
Acquire Data: Bandwidth	.05 – 35 Hz –3db	.05 – 35 Hz –3db	ER300: .5 –35 Hz ER310/320: .05– 30 Hz	.05 – 30 Hz
Input Impedance	>5M ohm	2M ohm	5M ohm	2M ohm
Signal Input Range	±2.5 mV	2 mV	±2 mV	±2mV
Common Mode Rejection	>60 db	60 db	Not available	60 db
ECG Channels	1	1	1 or 2	ER710 – 1, ER720 - 2
Digitize Data: Resolution	8 bit	15.6 μV	8 bit	8 bit
Sample Rate	128 samples/sec	218 Hz	120/sec.	120/sec.
Record Data Looping memory	Yes	Yes	ER300: No (post) ER310/320: Yes	Yes
Memory Type	Flash	Microprocessor based	RAM	Flash
Max. Recording Duration	360 sec.	300 sec.	ER300: 270 sec., ER310: 240 pre/135 post ER 320: 240 pre/100 post	1 channel: 955 sec. 2 channels: 477 sec.
Maximum # of Events	2	60	2	120

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Specification	Datrix E-Tac EX-1000	Instromedix King of Hearts	Braemar ER 300 series	Braemar ER 700 series
Operational Principles (continued): Data Transmission:	Transtelephonic (TTP) FM Modulation, FSK	Transtelephonic (TTP) FM Modulation, FSK	Transtelephonic (TTP) FM Modulation	Transtelephonic (TTP) FM Modulation; or download to PC, RS232
Center Frequency	1900 Hz	1900 Hz	1900 Hz	1900 Hz
Deviation	100 Hz/mV	100 Hz/mV	100 Hz/mV	100 Hz/mV
Transmission Speed	1x or 3x	1x or 3x	1x	1x or 3x
User Interface Start recorder	Insert batteries, insert leadwires	Insert batteries, insert leadwires	ER300: Insert battery, press [Record] and [Play] buttons at same time ER310/320: Insert battery, press [On/Erase] button	Insert batteries, insert leadwires
Recording	Press [Record] button	Press [Record] button	ER300: Press [Record] button ER310/320: Press [Play/Record] button	Press [Event/Send] button
Transmit Data	Remove leadwires, press [Send] button	Remove leadwires 1x: press [Send] button 3x: press [Send] and [Record] buttons sequence	ER300: Press [Play] button ER310/320: remove leadwires, press [Play/Record] button	Remove leadwires, press [Send] button
Erase Data	Following transmission or startup, insert leadwires	Following transmission, insert leadwires	ER300: Press [Play] and [Record] buttons together ER310/320: Press [On/Erase]	Following transmission, insert leadwires
Feedback	LED, audible tones	LCD, audible tones	ER300: audible tones ER310/320: LED, audible tones	LCD, audible tones
Selectable/programmable	Dipswitches	Insert program key, select using buttons	Various sequence of buttons	Insert program plug, select using buttons

Specification	Datrix E-Tac EX-1000	Instromedix King of Hearts	Braemar ER 300 series	Braemar ER 700 series
Power Requirements				
Battery	2 - AAA alkaline	2 - AAA alkaline	9V alkaline	2 - AAA alkaline
Battery Life	30 days	7 days	ER300: 30days, ER310/320: 19 days	7 days
Physical Specs				
Dimension, inches	2.5 x 1.6 x 0.57	3.38 x 2.13 x 0.65	ER 300: 4.15 x 2.39 x 1.06 ER 310/320: 4.15 x 2.39 x 0.86	3.5 x 2.125 x .65
Weight (w/batteries)	1.5 oz.	3.5 oz.	ER 300: 5.6 oz. ER 310/320: 3 oz.	3.5 oz.
Color	Black	Black	Black	Black
Enclosure	ABS, IPX0	Not available	Molded Plastic (UL94V-0)	Molded Plastic (UL94V-0)
Environmental				
Operating Temp.	0-45° C	10-40°C	0-45° C	0-45° C
Storage Temp.	-20-65° C	-10 - +60°C	-20 - +65° C	-20-+65° C
Operating Humidity (non-condensing)	5–95%	10–95%	10–95%	10– 95%
Non-operating Humidity	5–95%	Not available	5–95%	5–95%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Datrix, Inc.
c/o Alfredo J. Quattrone, Ph.D., D.A.B.T.
California Department of Health Services
Food and Drug Branch
Medical Device Safety Section, MS 7602
1500 Capitol Avenue
Sacramento, CA 95814

Re: K042022
Trade Name: Datrix E-Tac EX-1000 ECG Event Recorder
Regulation Number: 21 CFR 870.2920
Regulation Name: DXH
Regulatory Class: II (two)
Product Code: Telephone Electrocardiograph Transmitter and Receiver
Dated: August 6, 2004
Received: August 9, 2004

Dear Dr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K042022

Device Name: Datrix E-Tac EX-1000 Electrocardiographic Event Recorder

Indications for Use: The Datrix E-Tac EX-1000 Electrocardiographic Event Recorder device is intended for long-term monitoring of ambulatory cardiac patients who experience intermittent symptoms associated with cardiac arrhythmia. Upon activation by the patient, ECG data are stored for future transmission via telephone to a receiving station. Data transmission is initiated by the patient and confirmed by the receiving station. Once data are transmitted, they are immediately available for review solely by a physician or other qualified medical professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescriptive Use X OR Over-The-counter Use _____

(Per 21 CFR 801.109)

Mark P Ogden for 502

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042022